

**Appl. No.** : **10/771,845**  
**Filed** : **February 4, 2004**

## **REMARKS**

Applicant initially would like to thank Examiners Melissa Ryckman and Jackie Ho for the courtesies extended Applicant's representatives during the personal interview held on November 12, 2009, summarized above.

By way of summary, Claims 1-7, 10-13, 15, 16, and 48-56 are pending in this application. In the outstanding Office Action of September 1, 2009, Claims 1-7, 10-13, 15, 16 and 48-56 were rejected under 35 U.S.C. §103(a) as unpatentable over Shaw (U.S. 6,080,182) in further view of Marino (U.S. 7,087,072). Claims 55 and 56 have been cancelled. Claims 1 and 10 have been amended.

### **I. Claim Amendments**

In this Amendment, Claims 1 and 10 have been amended to further define the subject matter for which protection is sought and to expedite issuance of a patent. The Applicant respectfully submits that the claims as previously pending are patentably distinguished over the cited references or any combination thereof. However, to expedite prosecution, Applicant has amended the claims in order to clarify the features of Applicant's claimed invention. Applicant reserves the right to pursue the previously unamended claims or claims of broader scope at a later date.

### **II. §103(a) Claim Rejection to Shaw et al. (U.S. 6,080,182) in further view of Marino (U.S. 7,087,072).**

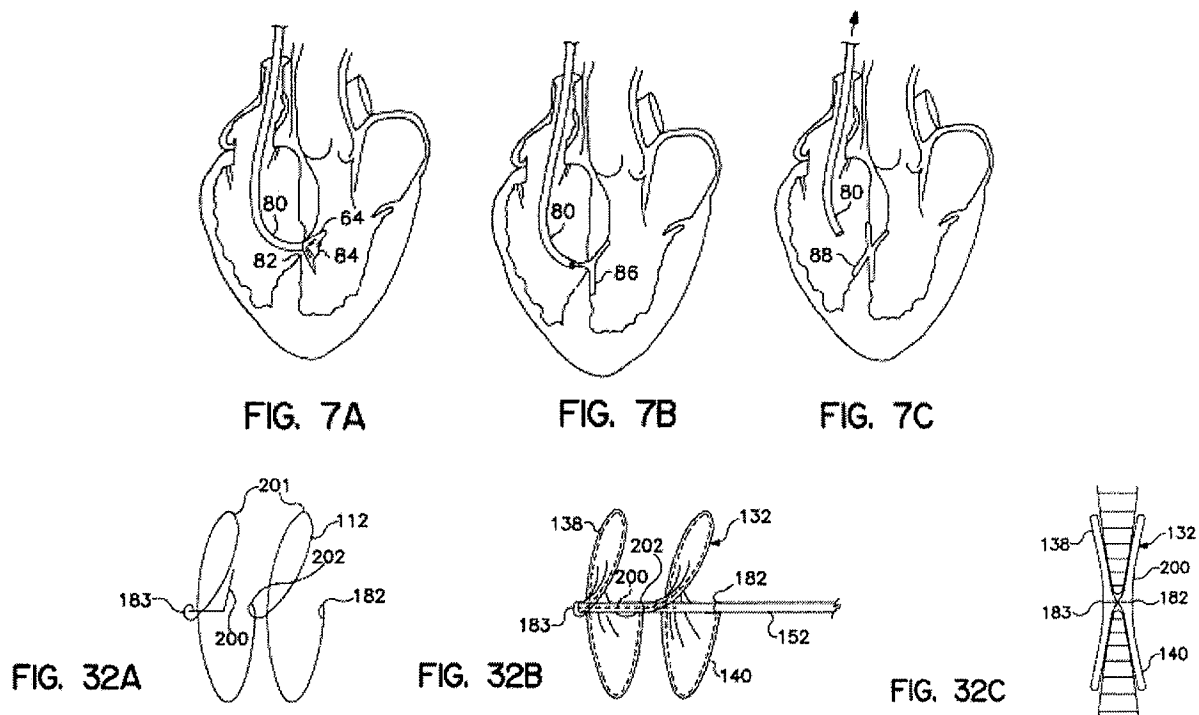
The Office Action of September 12, 2008 rejects Claims 1-7, 10-13, 15, 16 and 48-56 under 35 U.S.C. §103(a) as unpatentable over Shaw in further view of Marino. Claims 55 and 56 have been cancelled.

#### **A. Shaw is not properly combinable with Marino**

The Office Action admits that Shaw "fails to specify the type of septal defect including a patent foramen ovale (PFO)" at page 5. The Office Action then makes a conclusory statement that "it would have been obvious to one of ordinary skill in the art to use the defect as shown in Marino with the device of Shaw as it is well known in the art that a PFO is a common defect as described in Marino, and that Shaw's device is applicable and effective for such a defect." Applicant respectfully disagrees with this conclusory statement, and rebuts the combination of

Shaw and Marino as improper, as it would require significant, non-obvious modifications to the Shaw device for it to work in a PFO, and one skilled in the art would have no reasonable expectation of success.

Shaw defines a defect as generally a hole in the wall of a tissue (Shaw, col. 1, ll. 23-29). In particular, Shaw is directed to block circular holes. Some of the Shaw Figures referenced in the office action include Figs. 7A-7C and Figs. 32A-32C. The cited Figures clearly show Shaw's device used in open, through holes with no overlapping tissues or overlapping septa:



As disclosed in Applicant's specification, the PFO is different from a general septal defect, which tends to be a through hole in a wall: "In contrast to other septal defects which tend to have a generally longitudinal axis, a patent foramen ovale tends to behave like a flap valve. Accordingly, the axis of the patent foramen ovale tends to be at an angle, and almost parallel to the septal wall." Applicant specification at [0009]. In other words, the PFO channel is formed by overlapping atrial septa, as recited by Applicant's present claims.

Shaw does not mention any PFO, septum primum, septum secundum, or any flap structure or channel formed between flaps associated with its septal defects. Moreover, it is not obvious that the Shaw device, designed for holes, can be used to close channels comprised of overlapping flaps that have different functional characteristics than those of simple through

holes. Shaw's device uses a wire helical under structure to spread out an occluder panel on each side of a circular hole in a septum. The PFO channel does not consist of a simple open circular hole in a tissue membrane—instead, the PFO channel is formed by overlapping atrial septa. One would not be motivated to place and use the devices of Shaw in a PFO because Shaw's helical wire structure would separate the flaps of the PFO, prying open the overlapping tissue to allow more fluid flow between the atria, thereby frustrating the purpose of the Shaw device.

For these reasons, Applicant respectfully disagrees with the combination of Shaw with Marino. The teachings of Shaw do not lead to predictable results since the Shaw device is not configured to deploy in a PFO. Shaw also cannot be modified with any reasonable expectation of success to work in a PFO because the Shaw helical structure would interfere with the closure of the PFO's overlapping flaps. Accordingly, Applicant submits that the device of Shaw can not properly be combined with the Marino reference for application in a PFO.

**B. Even if combined, Shaw and Marino fail to teach or suggest aspects of the Claims**

Amended Claim1 recites, in part, “wherein the closure device when locked exerts a force to draw the septum primum and septum secundum together in an overlapping configuration to close the channel formed between the overlapping proximal surface of the septum primum and the distal surface of the septum secundum; wherein the locking element remains at the patent foramen ovale after locking.” Amended Claim10 recites, in part, “wherein the closure device when deployed exerts a force to draw the overlapping septum primum and septum secundum together in an overlapping configuration to close the channel disposed between the overlapping proximal surface of the septum primum and the distal surface of the septum secundum; wherein the locking element remains at the patent foramen ovale after locking.” As discussed in the Interview, Shaw fails to disclose, teach or suggest these features of the amended claims.

Page 3 of the Office Action argues that the Shaw “closure device when deployed exerts a force to draw the septum primum and septum secundum together (Figs. 7, 32C).” Claims 1 and 10, as amended, recite in part, “an overlapping configuration.” Shaw's septa in Figs. 7 and 32C are not overlapping, rather they are positioned one above the other as edges of a hole, as drawn in Shaw's figures. In this orientation, the clamping force of the Shaw device cannot draw these septa closer together. The Shaw closure device when deployed exerts a force in a direction normal to the plane of the septa. Thus, Shaw's closure device may squeeze the edge on both

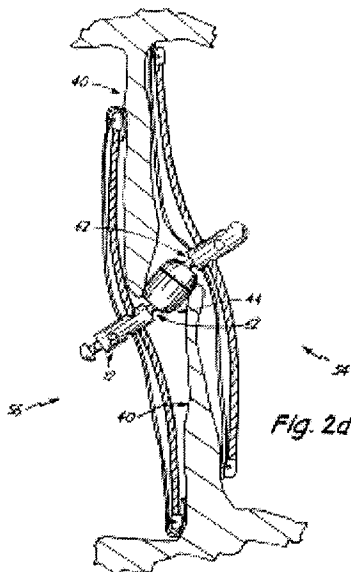
sides of a planar hole septal defect, but it does not “draw the septum primum and septum secundum together” as recited in Claims 1 and 10.

The Office Action indicates that once the flexible inner tube 152 is removed the Shaw “locking element” locks. Claim 1 and Claim 10 recite, in part, “wherein the locking element remains at the patent foramen ovale after locking.” Thus, as stated in the Office Action, Shaw’s disclosure that “removal of 152 causes the element to lock” cannot result in “the locking element remain[ing] at the patent foramen ovale after locking.”

Marino fails to address the deficiencies of the Shaw reference. Marino teaches away from a locking element as claimed by disclosing a device with an articulating center post “which allows the device to better conform to the contours of the heart.” Marino Abstract and col. 1, lines 18-21. Marino describes the center section 12, shown in Figure 2d reproduced below, as flexible and articulated:

The center section 12 shown in the device 10 is **articulated**. The articulation can be accomplished by a variety of methods. The articulation could comprise one or more joints, or hinges. It could also be a spring or a coil. Additionally, a spot specific reduction in the amount of material used to create the center section 12 could render portions of the section 12 sufficiently **flexible**.

Marino col. 3, lines 10-16.



Marino discusses that advantages of the center section being articulated or flexible are that it allows “the joint 62 to move” and that it “allows the distal and proximal sides 54, 56 to conform more readily to the contours of the heart 31.” Marino col. 4, lines 42-49; col. 5, line 64 – col. 6,

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line 1. Accordingly, Marino at least does not teach or suggest the recited “locking element” of Claims 1 and 10.

Moreover, Claim 1 further recites that “the closure device is self-expandable to a deployment shape wherein the proximal, intermediate and distal segments are generally parallel to one another.” Because of the articulation at the joint 62 as described above, Marino fails to teach or suggest a structure that is self-expandable to a deployment shape wherein the proximal, intermediate and distal segments are generally parallel to one another.

Claim 10 further recites that “when the closure device is in its elongate configuration the proximal and distal ends are pulled away from each other and when the closure device is in its clip configuration the closure device has generally an S-shape.” Applicant respectfully submits that this structure is neither taught nor suggested by Marino.

For at least the foregoing reasons, Applicant respectfully submits that independent Claims 1 and 10 are not rendered obvious by the proposed combination of Shaw with Marino. The remaining rejected claims under Shaw in view of Marino (2-7, 11-13, 15, 16 and 48-54) depend from one of independent Claims 1 and 10 and are allowable for the same reasons set forth above with respect to Claims 1 and 10 in addition to the patentable subject matter contained therein. Accordingly, withdrawal of the §103 rejections based on Shaw in view of Marino regarding Claims 1-7, 10-13, 15, 16 and 48-54 (as Claims 55 and 56 are cancelled) is respectfully requested.

### **III. No Disclaimers or Disavowals**

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

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#### **IV. Co-Pending Applications of Assignee**

Applicant wishes to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

<b>Serial Number</b>	<b>Title</b>	<b>Filed</b>	<b>Matter Reference</b>
11/927448	TISSUE OPENING OCCLUDER	10/29/2007	EV3.062C1
10/419412	SEPTAL DEFECT OCCLUDER	4/21/2003	EV3.058CPC1
10/227773	DEFECT OCCLUDER RELEASE ASSEMBLY AND METHOD	8/26/2002	EV3.059C1
12/110186	RETRIEVABLE SEPTAL DEFECT CLOSURE DEVICE	4/25/2008	EV3.067C1C1
10/972635	PATENT FORAMEN OVALE CLOSURE SYSTEM	10/25/2004	EV3.079A
10/783783	DEVICES AND METHODS FOR CLOSING A PATENT FORAMEN OVALE WITH A COIL-SHAPED CLOSURE DEVICE	2/20/2004	MVMDINC.060A
10/841880	DEVICES AND METHODS FOR CLOSING A PATENT FORAMEN OVALE USING A COUNTERTRACTION ELEMENT	5/7/2004	MVMDINC.068A

#### **V. Conclusion**

Applicant respectfully submits that the claims are in condition for allowance. Furthermore, any remarks in support of patentability of one claim should not be imputed to any other claim, even if similar terminology is used. Any remarks referring to only a portion of a claim should not be understood to base patentability on that portion; rather, patentability must rest on each claim taken as a whole. Applicant respectfully traverses each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches, even if not expressly discussed herein.

Applicant respectfully requests that a Notice of Allowance be issued at the earliest opportunity. However, if the Examiner has any questions or concerns, the Examiner is invited to telephone Applicant's attorney of record so that extended prosecution of this application may be avoided.

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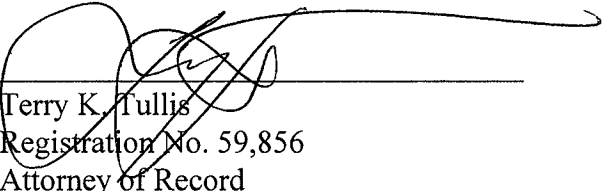
Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: 11-30-09

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